

K941784

510(k) Summary of Safety and Effectiveness

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This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SDMA 1990 and 21 CFR 807.92.

Ventana Medical Systems, Inc. developed Ventana Anti-CD8 (Clone SFC121Thy2D3) for use on the Ventana ES automated immunohistochemistry system. Ventana Anti-CD8 (Clone SFC121Thy2D3) is substantially equivalent to antibodies detecting cellular elements of lymphocytic origin as reported by Reinherz, et al.<sup>1</sup>

### Comparative Study

Supporting data for the equivalence statement is shown by the following study. Frozen preparations from normal and pathologic samples were tested using Ventana Anti-CD8 (Clone SFC121Thy2D3). Samples were obtained from excess tissues obtained for reasons other than the present study. Pathologic and normal tissues were examined. Slides were processed on the Ventana ES Automated Slide Stainer, prepared for examination, and evaluated by a qualified pathologist for specific staining intensity and background staining.

### Results

Staining occurred on the surface of lymphoid cells from normal tonsil, thymus and blood. Negative control tissue was all negative. There was no inappropriate staining of the tissues in this study.

Sensitivity of the antibody was shown with appropriate staining of cells of lymphoid origin and no staining of cells of non-lymphoid origin. In addition, the Ventana data in this study agrees with the data published by Reinherz *et.al.*<sup>1</sup> and Deegan<sup>2</sup>.

The reactivity of this antibody was shown by consistent staining of 9 of 9 T cell lymphomas, and appropriate staining of normal lymphoid tissues (9 of 9 blood smears, 4 of 4 peripheral blood lymphocyte cytopspins, 4 of 4 thymus tissues and 10 of 10 tonsil tissues). As with any immunohistochemical reagent, the sensitivity is dependent on tissue processing and slide preparation parameters. The negative control which was run with each tissue gave negative results.

Inter-run reproducibility was determined by using the same positive control (frozen tonsil) on each of 10 different instrument runs. All ten slides stained positively for CD8 antigen.

Intra-run reproducibility was determined based on ten samples of the same frozen tonsil tissue within one run. All ten slides stained positively for CD8 antigen.

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<sup>1</sup>Reinherz EL, Hussey RE, Fitzgerald K, Snow P, Terhorst C and Schlossman SF: Antibody directed at a surface structure inhibits cytolytic but not suppressor function of human T lymphocytes. *Nature* 1981, 294:168-170.

<sup>2</sup>Deegan Michael J: Membrane antigen analysis in the diagnosis of lymphoid leukemias and lymphomas. *Arch Pathol Lab Med* 1989, 113:606-618.

Revised on December 10, 1996